

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

RICHARD F. SELDEN,

Defendant.

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**Civil Action No.
05 CV 11805 NMG**

PLAINTIFF’S MOTION FOR ENTRY OF FIVE-YEAR BAR ORDER

Plaintiff, the Securities and Exchange Commission (“SEC”), hereby moves pursuant to Paragraph V of the final judgment for an order barring defendant Richard F. Selden from serving as an officer or director of a public company for five years. Grounds for this motion are set forth in the accompanying memorandum of law.

REQUEST FOR ORAL ARGUMENT

In accordance with Local Rule 7.1(D), the Commission hereby requests oral argument in support of this motion.

Respectfully submitted,
**SECURITIES AND EXCHANGE
COMMISSION,**

By its attorneys,

/s/ R.M. Harper II

Frank C. Huntington (BBO No. 544045)

Senior Trial Counsel

Richard M. Harper II (BBO No. 634782)

Senior Trial Counsel

Robert B. Baker (BBO No. 654023)

Staff Attorney

33 Arch Street, 23rd Floor

Boston MA 02110
(617) 573-8900
(617) 573-4590 (facsimile)

Dated: September 2, 2008

CERTIFICATE OF SERVICE

I, Richard M. Harper II, certify that on September 2, 2008, the forgoing Plaintiff's Motion for Entry of Five-Year Bar Order was filed electronically with the Court. Notice will be sent by email to all parties through the Court's electronic filing system, and the filing may be accessed through the Court's system. In addition, the undersigned has caused a paper copy to be served by first-class mail to defendant's counsel of record:

Justin J. Daniels, Esq.
Thomas J. Dougherty, Esq.
SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
One Beacon Street
Boston, Massachusetts 02108

Attorneys for defendant Richard F. Selden

/s/R.M. Harper II _____
Richard M. Harper II

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

RICHARD F. SELDEN,

Defendant.

Civil Action No.
05 CV 11805 NMG

DECLARATION OF RICHARD M. HARPER II, ESQ.
IN SUPPORT OF PLAINTIFF'S
MOTION FOR ENTRY OF FIVE-YEAR BAR ORDER

Richard M. Harper II, Esq., hereby declares, pursuant to 28 U.S.C. § 1746, that the following is true and correct:

1. I am an attorney and a member in good standing of the bars of the Commonwealth of Massachusetts and the State of Hawaii. I am a Senior Trial Counsel in the Boston Regional Office of plaintiff Securities and Exchange Commission (the "Commission"), and counsel to the Commission in this enforcement action.

2. Attached as Exhibit A is a true and accurate copy of the 2007 Annual Report for Network Biosystems, Inc., which was filed with the Massachusetts Secretary of State's Office on January 14, 2008.

3. Attached as Exhibit B is a true and accurate copy of the Network Biosystems, Inc. "Home" Webpage, located at <http://www.networkbiosystems.com/default.asp>.

4. Attached as Exhibit C is a true and accurate copy of Transkaryotic Therapies, Inc.'s Form 8-K Current Report and Exhibit 99.1, filed with the Commission on January 4, 2001.

5. Attached as Exhibit D is a true and accurate copy of pages 1-12, 93-100, and 145-60 of the deposition testimony of Thomas J. Schuetz, M.D.

Executed under the pains and penalties of perjury this 2nd day of September, 2008, at Boston, Massachusetts.


Richard M. Harper II, Esq.

EXHIBIT A

MA SOC Filing Number: 200805568970 Date: 01/14/2008 2:59 PM



The Commonwealth of Massachusetts
William Francis Galvin

Minimum Fee: \$100.00

Secretary of the Commonwealth
 One Ashburton Place, Boston, Massachusetts 02108-1512
 Telephone: (617) 727-9640

Annual Report

(General Laws, Chapter 156D, Section 16.22; 950 CMR 113.57)

Federal Employer Identification Number: 043525704 (must be 9 digits)1. Exact name of the corporation: NETWORK BIOSYSTEMS, INC.2. Jurisdiction of Incorporation: State: DE Country: USA

3,4. Street address of the corporation registered office in the commonwealth and the name of the registered agent at that office:

Name: DAVID CHAO
 No. and Street: 1 B GILL ST.
 City or Town: WOBURN State: MA Zip: 01801 Country: USA

5. Street address of the corporation's principal office:

No. and Street: 1 B GILL ST.
 City or Town: WOBURN State: MA Zip: 01801 Country: USA

6. Provide the name and business street address of the officers and of all the directors of the corporation:
 (A president, treasurer, secretary and at least one director are required.)

Title	Individual Name First, Middle, Last, Suffix	Address (no PO Box) Address, City or Town, State, Zip Code
PRESIDENT	MARY CONSALVI	564 MCKINLEY TERRACE CENTERPORT, NY 11721 USA
TREASURER	MARY CONSALVI	564 MCKINLEY TERRACE CENTERPORT, NY 11721 USA
SECRETARY	MARY CONSALVI	564 MCKINLEY TERRACE CENTERPORT, NY 11721 USA
CEO	RICHARD F SELDEN PH.D	21 HUCKLEBERRY HILL LINCOLN, MA 01773 USA
DIRECTOR	GARY MAGNANT PH.D.	47 FOX RUN ROAD TOPSFIELD, MA 01983 USA
DIRECTOR	PAUL MATSUDAIRA PH.D	78 NONATUM ST. NEWTON, MA 02458 USA

7. Briefly describe the business of the corporation:

DEVELOPMENT STAGE BIOTECH/HIGH TECH COMPANY

8. Capital stock of each class and series:

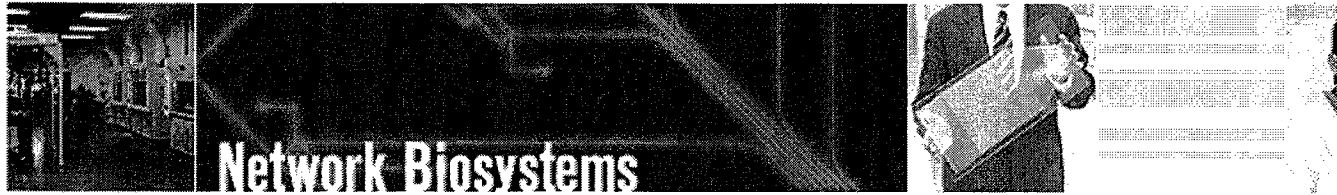
Class of Stock	Par Value Per Share Enter 0 if no Par	Total Authorized by Articles of Organization or Amendments		Total Issued and Outstanding <i>Num of Shares</i>
		<i>Num of Shares</i>	<i>Total Par Value</i>	
CWP	\$0.01000	400,000	\$4,000.00	121,263

9. Check here if the stock of the corporation is publicly traded: ☐

10. Report is filed for fiscal year ending: 12/31/ 2007

Signed by MARY CONSALVI, its PRESIDENT
on this 14 Day of January, 2008

EXHIBIT B

[HOME](#)[CONTACT US](#)

Network Biosystems is a development stage biotech/high tech company developing nanotechnology and microfluidics for DNA analysis in clinical, forensic, and genomic applications. Privately held and founded based on pioneering research performed at MIT's Whitehead Institute, NetBio fuses microelectronics and biotechnology to build "bio/nanotech" systems that sense and manipulate the physical world.

The Company has several broadly enabling technology platforms, all based on the integration of nanotechnology and microfluidics with biotechnology and molecular biology:

- **Clinical Diagnostics:** Network Biosystems believes that the real-time sequencing of patient samples in the hospital laboratory will have a dramatic impact on clinical decision making.
- **Forensics:** Network Biosystems is commercializing a rugged, portable STR identification instrument that functions both at the crime scene as well as the forensic laboratory.
- **Homeland Security:** Network Biosystems' instrumentation for the rapid, on-site screening of large numbers of individuals has a broad application to homeland security.
- **Genomic Sequencing:** Large scale, high capacity sequencing of the human genome in the academic and pharmaceutical settings.

For further information, please contact:

Mary Consalvi, President
Phone +1 (781) 938-6014
Email mary@networkbiosystems.com

Network Biosystems

1 Gill Street, Suite B Woburn, MA 01801 USA 781-938-6060 T 781-938-6062 F

www.networkbiosystems.com

EXHIBIT C

<DOCUMENT>
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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): JANUARY 3, 2001

TRANSKARYOTIC THERAPIES, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation)

000-21481

(Commission File Number)

04-3027191

(IRS Employer Identification No.)

195 ALBANY STREET, CAMBRIDGE, MASSACHUSETTS

02139

(Address of Principal Executive Offices)

(Zip Code)

(617) 349-0200

Registrant's Telephone Number, Including Area Code

NOT APPLICABLE

(Former Name or Former Address, if Changed Since Last Report)

<PAGE>

Item 5. OTHER EVENTS.

On January 3, 2001, Transkaryotic Therapies, Inc. ("TKT") announced that it has received a complete review letter from the U.S. Food and Drug Administration (FDA) concerning its Biologics License Application (BLA) for Replagal(TM) (agalsidase alfa), an investigational enzyme replacement therapy for the treatment of Fabry disease. In the letter, the FDA has asked for further explanation in several areas and requested additional data. TKT has initiated the collection of these data, but until there is an opportunity for further discussion with the FDA, TKT cannot make projections about the timing of future FDA decisions concerning the approval of Replagal.

The full text of TKT's press release issued in connection with the foregoing matter is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS.

(c) Exhibits.

99.1 Press Release

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<PAGE>

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 4, 2001

REGISTRANT

TRANSKARYOTIC THERAPIES, INC.

By: /s/ DANIEL E. GEFFKEN

Daniel E. Geffken
Vice President, Finance and
Chief Financial Officer

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EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
99.1	Press Release

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EXHIBIT 99.1

FOR IMMEDIATE RELEASE

TKT RECEIVES FDA COMPLETE REVIEW LETTER ON REPLAGAL-TM-

CAMBRIDGE, MA, JANUARY 3, 2001 --- Transkaryotic Therapies, Inc. (Nasdaq: TKTX) today announced that it has received a complete review letter from the U.S. Food and Drug Administration (FDA) concerning its Biologics License Application (BLA) for Replagal-TM- (agalsidase alfa), an investigational enzyme replacement therapy for the treatment of Fabry disease. In the letter, the FDA has asked for further explanation in several areas and requested additional data. TKT has initiated the collection of these data, but until there is an opportunity for further discussion with the FDA, TKT cannot make projections about the timing of future FDA decisions concerning the approval of Replagal.

"While we are disappointed that the FDA did not approve Replagal at this time, we are working diligently to respond quickly to their requests for additional data," stated Richard F Selden, M.D., Ph.D., President and Chief Executive Officer of TKT. "We believe Replagal is the best hope for patients suffering from this life-threatening disease, and we remain firmly committed to bringing a safe and effective therapy to market for the thousands of patients affected by Fabry disease. We will continue to do everything we can to make this therapy available as soon as possible and we look forward to working with the FDA towards attaining this goal."

The BLA submission was based on data generated from two independent pivotal studies, conducted at the National Institutes of Health (NIH) and Royal Free Hospital in the United Kingdom, as well as long-term data from an additional six months of treatment from an open-label maintenance study at the NIH. Data from the pivotal NIH study were presented at the 50th Annual Meeting of the American Society of Human Genetics in October 2000. Data generated from the United Kingdom study will be presented at an upcoming medical meeting.

About Fabry Disease

Fabry disease is an inherited rare genetic disorder caused by deficient activity of the lysosomal enzyme alpha-galactosidase A. In patients with Fabry disease, globotriaosylceramide (Gb3) accumulates in various organs and tissues of the body due to the deficiency of alpha-galactosidase A. As a result, the deposits of this material can result in extreme pain, severe kidney damage, cardiovascular disease, and stroke. Due to its rarity and vast array of symptoms, diagnosis is often difficult and affected individuals have a significantly reduced quality of life and a greatly shortened life expectancy. TKT estimates that approximately 5,000 patients worldwide are affected by Fabry disease.

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About TKT

Transkaryotic Therapies, Inc. (TKT) is a biopharmaceutical company dedicated to the development and commercialization of products based on its three proprietary development platforms: Gene-Activated-Registered Trademark- proteins, Niche Protein-TM- products, and Gene Therapy. The Company's gene activation technology is a proprietary approach to the large-scale production of therapeutic proteins, which does not require the cloning of genes and their subsequent insertion into non-human cell lines. TKT's Niche Protein product platform is based on protein replacement for the treatment of rare genetic diseases, a group of disorders characterized by the absence of certain metabolic enzymes. The Company's Gene Therapy technology, known as Transkaryotic Therapy-TM-, is focused on the commercialization of non-viral, ex vivo gene therapy products for the long-term treatment of chronic protein deficiency states.

This press release contains forward-looking statements that involve a number of risks and uncertainties. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words, "believes," "anticipates," "plans," "expects," "intends," and similar expressions are intended to identify forward-looking statements. Important factors that could cause actual results to differ materially from the expectations described in these forward-looking statements are set forth under the caption "Certain Factors That May Affect Future Results" in TKT's Annual Report on Form 10-K for the year ended December 31, 1999 and updated in TKT's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, which are both on file with the Securities and Exchange Commission and incorporated herein by reference. These important factors include risks as to whether TKT's products, such as Replagal, will advance in the clinical trials process, the timing of such clinical trials, whether the clinical trial results will warrant continued product development, and whether TKT's products, such as Replagal, will receive approval from the U.S. Food and Drug Administration or equivalent regulatory agencies, and, if such products receive approval, whether they will be successfully marketed; the results of any patent litigation in which TKT is involved or may become involved; competition; and TKT's dependence on collaborators.

Gene-Activated-Registered Trademark- is a registered trademark and Niche Protein-TM-, Replagal-TM-, TKT-TM-, and Transkaryotic Therapy-TM- are trademarks of Transkaryotic Therapies, Inc.

Please visit our web site at www.tktx.com for additional information about Transkaryotic Therapies, Inc.

CONTACT:

Justine E. Koenigsberg
Manager, Corporate Communications
(617) 349-0271

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EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 05-11805-NMG

SECURITIES AND EXCHANGE COMMISSION,
Plaintiff,

vs.

RICHARD F. SELDEN,
Defendant.

CONFIDENTIAL VIDEOTAPE DEPOSITION

OF THOMAS J. SCHUETZ, M.D., taken pursuant to
the applicable provisions of the Federal Rules
of Civil Procedure, before Marsha S. Gerber,
RPR, CSR No. 111793, and Notary Public in and
for the Commonwealth of Massachusetts, at the
offices of Securities and Exchange Commission,
33 Arch Street, Boston, Massachusetts, on
Friday, September 28, 2007, commencing at
9:36 a.m.

KACZYNSKI REPORTING
72 CHANDLER STREET, SUITE 3
BOSTON, MASSACHUSETTS 02116

I N D E X

WITNESS EXAMINATION
THOMAS J. SCHUETZ, M.D.
By Mr. Huntington 5, 290
By Mr. Dougherty 156, 316

E X H I B I T S

SEC NUMBER	PAGE
38	Copy of Subpoena 4
39	Copy of portion of BLA 26
40	Copy of memo of 9/22/98 to file from James Kaiser 62
41	Copy of letter of 12/7/98 to Dr. Schiffmann from Dr. Schuetz 66
SELDON NUMBER	PAGE
70	Copy of document 208
71	Copy of CPMP Assessment Report 245

Exhibits retained by Attorney Huntington

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APPEARANCES:

FRANK C. HUNTINGTON, ESQUIRE
United States Securities and
Exchange Commission
Boston District Office
33 Arch Street
Boston, Massachusetts 02110
For the Plaintiff

THOMAS J. DOUGHERTY, ESQUIRE
JUSTIN J. DANIELS, ESQUIRE
SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
One Beacon Street
Boston, Massachusetts 02108-3194
For the Defendant

DAVID E. MARDER, ESQUIRE
ROBINS, KAPLAN, MILLER & CIRESI, LLP
800 Boylston Street, 25th Floor
Boston, Massachusetts 02199-7610
For the Deponent

ALSO PRESENT:

THOMAS M. LAUB, VIDEOGRAPHER
NATIONAL VIDEO REPORTERS, INC.
58 Battery March Street, Suite 243
Boston, Massachusetts 02110

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PROCEEDINGS

(Exhibit Number SEC 38
marked for Identification)

THE VIDEOGRAPHER: We are
now recording and on the record. My
name is Thomas Laub. I'm the video
legal specialist for National Video
Reporters. Our business address is 58
Battery March Street, Suite 243, Boston,
Massachusetts 02110. Today is
September 28th, 2007, and the time is
9:36 a.m.

This is the deposition of
Thomas Schuetz in the matter of
Securities and Exchange Commission,
plaintiff, versus Richard Selden,
defendant, in the U.S. District Court,
District of Massachusetts, Case Number
05-11805-NMG. This deposition is being
taken at 33 Arch Street, Boston,
Massachusetts.

The court reporter is
Marsha Gerber of Kaczynski Reporting.

1 Counsel will state their appearances,
2 and the court reporter will administer
3 the oath.

4 MR. HUNTINGTON: Frank
5 Huntington for the plaintiff,
6 Securities and Exchange Commission.

7 MR. DOUGHERTY: Thomas
8 Dougherty and Justin Daniels for the
9 defendant, Richard Selden.

10 MR. MARDER: David Marder
11 for the witness from Robins, Kaplan,
12 Miller & Ciresi.

13 Do I need a microphone?

14 THE VIDEOGRAPHER: No.

15 MR. MARDER: Okay.

17 THOMAS J. SCHUETZ, M.D.,
18 having been satisfactorily identified and
19 sworn by the Notary Public, was examined
20 and testified as follows:

21 BY MR. HUNTINGTON:

22 Q Good morning, Dr. Schuetz.

23 A Good morning.

24 Q My name is Frank Huntington, and I'm an

1 is testifying here today in response to
2 the subpoena?

3 MR. MARDER: Yes.

4 Q And that was a clue that you're going
5 to need to respond verbally and not nod
6 or shake your head, --

7 A Okay.

8 Q -- and we do need to take turns and try
9 to let me finish before you talk, and
10 I'll try to let you finish before I ask
11 the next question. It will make it
12 easier for the reporter.

13 All right. So you are here
14 in response to the subpoena. Can I --
15 Some background information. Can you
16 tell us where you live?

17 A I live -- My address?

18 Q Yes, please.

19 A 62 Lexington Street in Framingham,
20 Massachusetts.

21 Q And can you briefly review for us your
22 education background after high school?

23 A I have a -- I did a bachelor of science
24 in chemistry at Xavier University in

1 attorney for the Securities and
2 Exchange Commission. I'll be asking
3 you some questions this morning to
4 start with.

5 If I ask you anything that
6 you don't understand, just let me know,
7 and I'll try to do better. If you need
8 to take a break at any point, just let
9 us know, and we can go off the record.

10 First of all, I'd just like
11 to show you a document that's been
12 marked as SEC Exhibit 38. Can you take
13 a moment to look at that and tell me if
14 you've seen it.

15 A I've not seen this.

16 MR. HUNTINGTON: Dave, can
17 we just have a stipulation that this is
18 the subpoena --

19 MR. MARDER: Sure. I'd
20 stipulate that this is a copy of the
21 subpoena that I accepted service of. I
22 did not provide it to the witness so
23 he's never seen it.

24 MR. HUNTINGTON: Okay. He

1 Cincinnati, Ohio. And after that I did
2 M.D. and Ph.D. degrees. The M.D.
3 degree is from Harvard Medical School,
4 and the Ph.D. is in genetics from
5 Harvard University.

6 Q Okay. And what year did you get the
7 degree from Xavier?

8 A 1983.

9 Q And did you get both degrees from
10 Harvard in the same year?

11 A Yes.

12 Q And what year was that?

13 A 1993.

14 Q And can you review for us briefly your
15 job history after that? You know,
16 where you worked and roughly what
17 years?

18 A Including medical training?

19 Q Yes, please.

20 A So I was a medical resident at
21 Massachusetts General Hospital from the
22 summer of 1993 until the summer of
23 1995. I was a medical oncology fellow
24 at the Dana Farber Cancer Institute

1 from the summer of 1995 until the
2 summer of 1998. During that time
3 period during the calendar year of 1997
4 inclusive I also was at Massachusetts
5 General Hospital again as the medical
6 chief resident, and I was -- also kept
7 my appointment at the Dana Farber
8 Cancer Institute during the calendar
9 year of 1997.

10 From the summer of 1998
11 until February of 2003 I was employed
12 at Transkaryotic Therapies, Inc. From
13 June of 2003 until November of 2006 I
14 was employed at Therion Biologics
15 Corporation. And over the past
16 approximately ten or eleven months I've
17 been self-employed as a consultant to
18 the -- as a medical consultant.

19 Q Do you have a particular specialty or
20 area of focus as an independent
21 consultant?

22 A No. I've been consulting to
23 principally biotech companies.

24 Q What kinds of subjects do the biotech

1 Q Okay. Do you know who at TKT actually
2 made the decision to make you an offer?

3 A No.

4 Q Okay. Now, what position did you have
5 when you started at TKT?

6 A My title was director clinical affairs.

7 Q Okay. And how long did you hold that
8 title?

9 A Approximately one year.

10 Q Did your title change --

11 A Yes.

12 Q -- after a year?

13 And what did it become?

14 A In approximately the summer of 1999 my
15 title became executive director
16 clinical affairs.

17 Q And did the title change again at some
18 point?

19 A Yes.

20 Q And when was that?

21 A In approximately the summer of 2000 my
22 title became vice president clinical
23 affairs.

24 Q Okay. Is that the title you had until

1 companies consult you about? Just
2 generally.

3 A Clinical trials. Clinical trial design
4 and evaluation of clinical trial data.

5 Q And I think the reporter might
6 appreciate it if I ask you, how do you
7 spell Therion, Therion Biologics?

8 A T-H-E-R-I-O-N.

9 Q Okay. Now, can you -- you started --
10 you said you started working at
11 Transkaryotic Therapies. And can we
12 refer to that as TKT today?

13 A Sure.

14 Q Okay. And you started at TKT in the
15 summer of 1998?

16 A Yes.

17 Q How did you come to be hired at TKT?

18 A In early 1998 I sent my resum out to
19 some biotech companies. I was
20 interested in exploring careers in
21 biotech, and I had -- TKT was one of
22 the companies that I sent my resum to.
23 And I had interviews there, and they
24 offered me a position.

1 you left the company in early 2003?

2 A Yes.

3 Q Okay. Now throughout that period did
4 you have the same basic job with the
5 company?

6 A Yes.

7 Q Okay. Can you tell us first generally
8 what your duties were in clinical
9 affairs regardless of the precise title
10 that they gave you?

11 A I was responsible for the clinical
12 trials that were being conducted with
13 TKT's therapeutics. Excluding the
14 products that had been partnered with
15 at the time Parks, Marion, Russell,
16 subsequently Aventis, but the products
17 -- TKT's products that were out
18 licensed were managed by the partnered
19 company. I managed the clinical trials
20 of TKT's proprietary compounds.

21 Q Okay. And I think you used the word
22 therapeutics?

23 A Yes.

24 Q What does that mean in this context?

1 some further clarification as to what
2 had happened?

3 A Yes.

4 Q All right. Let me show you what was
5 previously marked as SEC Exhibit 30.

6 Can you tell me if you've
7 seen SEC Exhibit 30 before?

8 A I have, yes.

9 Q What is SEC Exhibit 30?

10 A It appears to be a copy of an abstract
11 that was submitted by Dr. Schiffmann
12 for a scientific meeting.

13 Q Can you tell from looking at it what
14 the scientific meeting was?

15 A Yes. It was the American Society of
16 Human Genetics meeting in Philadelphia
17 in October of 2000.

18 Q Did you attend some or all of that
19 meeting of the American Society of
20 Human Genetics or the ASHG?

21 A Yes. I attended some of the meeting,
22 yes.

23 Q And did Dr. Schiffmann make a
24 presentation --

1 Q Is there some sort of booklet of
2 abstracts for all --

3 A Yes.

4 Q -- a variety of presentations?

5 A Yes.

6 Q Including this one?

7 A Yes.

8 Q Okay. Now, do you know who actually
9 wrote the text that is the one long
10 paragraph in the center of SEC
11 Exhibit 30?

12 A Yes.

13 Q Who wrote that text?

14 A Dr. Schiffmann, Dr. Selden, and I were
15 the principal authors of this.

16 Q Did one of you prepare a first draft?

17 A Yes.

18 Q Who was that?

19 A To the best of my recollection it was
20 Dr. Schiffmann.

21 Q So Dr. Schiffmann put together a first
22 draft, and then you and Dr. Selden
23 provided comments?

24 A Yes.

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1 A Yes.

2 Q -- at some point during the
3 conference?

4 A Yes.

5 Q Okay. And what's the connection
6 between the presentation he made and
7 this one-page document that is SEC
8 Exhibit 30?

9 A This a document that is submitted to
10 the Society by the clinical
11 investigator for the purposes of
12 determining whether or not this
13 abstract would be accepted to be
14 presented at the meeting. This
15 abstract was accepted and was accepted
16 as an oral presentation, and
17 Dr. Schiffmann gave a presentation that
18 was a more detailed presentation of
19 this abstract summary of that
20 presentation.

21 Q And did this abstract summary, this
22 one-page document, appear in some
23 materials for the conference?

24 A Yes.

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1 Q Okay. Do you recall any comments that
2 you provided?

3 A Specific comments?

4 Q Yes.

5 A I don't recall any specific comments
6 that I provided.

7 Q Do you recall any specific comments
8 that you understand Dr. Selden
9 provided?

10 A I don't recall any of his specific
11 comments. I'm sorry.

12 Q Okay. Now, in the middle of the
13 document there's some data about pain
14 at its worst scores. Do you see --
15 Right about in the middle of the
16 paragraph.

17 A Yes.

18 Q And there's a sentence -- there's some
19 data, and then there's a sentence that
20 says, the difference between the groups
21 was significant, P equals 0.021.

22 Do you see that?

23 A Yes.

24 Q Now that was one of the pain

1 calculations that we looked at earlier
 2 when we were looking at the TKT003
 3 portion of the BLA?
 4 A Yes.
 5 Q There were several other pain
 6 calculations that we looked at also
 7 that were also results of TKT003;
 8 correct?
 9 A Yes.
 10 Q And this is not the one that was
 11 identified at the outset as the primary
 12 endpoint calculation, is it?
 13 MR. DOUGHERTY: Object to
 14 the form of the question.
 15 A This --
 16 Q This -- I'll try again.
 17 A Okay.
 18 Q The particular data and P value that
 19 are listed here are not the calculation
 20 that was the -- designated as the
 21 primary endpoint for TKT003; isn't that
 22 right?
 23 MR. DOUGHERTY: Objection
 24 to the form of the question.

1 Q That's all right.
 2 MR. MARDER: You can
 3 answer.
 4 A Oh, okay. So the primary endpoint was
 5 the effect on pain.
 6 Q Right.
 7 A And there were several statistical
 8 analyses of that data that form the
 9 primary endpoint. This was one of
 10 those. It was not the single
 11 statistical calculation that had been
 12 designated as the single calculation of
 13 that data.
 14 Q Right.
 15 As we saw, when you were
 16 looking at SEC Exhibit 39, a
 17 calculation -- the area under the curve
 18 calculation that ended up with a P
 19 value of 0.081 was the calculation that
 20 you just referred to; correct?
 21 A Yes.
 22 MR. DOUGHERTY: Object to
 23 the form of the question.
 24 Q Okay. Do you know how it came to be

1 that the only pain value that appears
 2 in this abstract is the pain valve with
 3 the P 0.021?
 4 A Yes.
 5 Q Can you tell us how that happened?
 6 A Dr. Selden and I discussed this many
 7 times, and Dr. Selden felt that
 8 presenting multiple statistical
 9 analyses of the data would be too
 10 confusing. Dr. Selden thought that a
 11 simpler approach to this would be
 12 clearer.
 13 Q Okay. If you are going to pick one,
 14 wouldn't it make sense to pick the one
 15 that was designated as the primary
 16 calculation, the area under the curve?
 17 MR. DOUGHERTY: Object to
 18 the form of the question.
 19 A Yes.
 20 Q Do you have an understanding as to why
 21 that was not -- Strike that.
 22 Did you express any view on
 23 that subject to Dr. Selden?
 24 A Yes.

1 Q What did you say to him and what did he
 2 say to you?
 3 A I told him that we should present the
 4 three main statistical analyses and
 5 explain them as such.
 6 Q And what did he say?
 7 A He said that we should just present
 8 this one.
 9 Q Now, a little bit further down there's
 10 a reference to renal glomerular. See
 11 if you can find that with a P value of
 12 less than 0.01. It's about a third of
 13 the way from the bottom.
 14 A Yes.
 15 Q Is that one of the four kidney scores
 16 that we talked about earlier that
 17 involved glomerular?
 18 A Yes.
 19 Q This is only one of the four. Was
 20 there any discussion about putting all
 21 four in the abstract?
 22 A Well, these abstracts have quite a
 23 strict word limit so it's not really
 24 possible to do that. So this is just

1 mentioned, were you at any other
 2 discussions about what data should or
 3 should not be in the article?
 4 A We had -- we had numerous discussions
 5 about that. Dr. Selden and I
 6 probably -- I mean, we reviewed drafts
 7 of this many, many times.
 8 Q I take it you disagreed with Dr. Selden
 9 about which of the pain measure -- pain
 10 calculations should be in the article?
 11 MR. DOUGHERTY: Object to
 12 the form and lack of foundation.
 13 MR. HUNTINGTON: Okay.
 14 Q You can answer.
 15 A We -- we discussed how much of the data
 16 should -- from the study should go in
 17 here. There was an enormous amount of
 18 data generated in the study, and there
 19 were I believe a couple of different
 20 publications that came out of the study
 21 I think. So some of the data went in
 22 some papers, some went in others. So
 23 how we sort of -- that was the
 24 substance of those discussions.

1 Q Did you have any understanding of who
 2 made the final call as to which data
 3 would be in or not in the article as
 4 to --
 5 A Oh, Dr. Selden made the final call.
 6 Q Okay. I'd like to show you what was
 7 previously marked as Selden Exhibit 36.
 8 Dr. Schuetz, have you seen
 9 Selden Exhibit 36 before?
 10 A Yes.
 11 Q Can you tell us what it is?
 12 A It is the FDA's so-called briefing
 13 document in preparation for an FDA
 14 advisory committee meeting that had
 15 been scheduled for September of 2002 to
 16 discuss the potential -- to discuss the
 17 data and possible approval of Replagal.
 18 This document contains FDA's complete
 19 summary of all of the data that we
 20 submitted to them at that time.
 21 Q Okay. And the date on the document
 22 appears to be August 26th, 2002.
 23 Do you see that?
 24 A Yes.

1 Q Is that about the time that you
 2 received it?
 3 A Yes.
 4 Q And what was your understanding of how
 5 an advisory committee meeting relates
 6 to the overall process of FDA approval?
 7 A Well, at the FDA advisory committee
 8 meeting the company would give a
 9 presentation and the FDA would give a
 10 presentation, and this presentation is
 11 in front of a panel of experts to whom
 12 are given a number of questions on
 13 which they need to opine. And when
 14 they do so, the FDA advisory
 15 committee's recommendations are then
 16 given to FDA as to whether or not they
 17 recommend the ultimate approval of the
 18 drug. FDA can take their advice or
 19 not. FDA generally takes the advice of
 20 the advisory committee in general.
 21 Q Now, after you received Selden
 22 Exhibit -- Well, first of all, how did
 23 you get a copy of Selden Exhibit 36?
 24 A I don't remember how I got the copy,

1 but it was given to me in preparation
 2 for the advisory committee.
 3 Q And at the time you got it the
 4 expectation was that the advisory
 5 committee would meet the next month,
 6 September of 2002?
 7 A Yes. It was scheduled for September of
 8 2002.
 9 Q And the company had an opportunity to
 10 submit its own briefing book and
 11 prepared one a few weeks later; is that
 12 right?
 13 A No. We -- I think we submitted ours
 14 before we got this I think. Our -- we
 15 needed -- I'm pretty sure the
 16 requirement is to submit it about a
 17 month ahead.
 18 Q Okay.
 19 A So I -- Do we have that document?
 20 Q I apologize. I do not have it in front
 21 of me. Mr. Dougherty may.
 22 MR. DOUGHERTY: We'll get
 23 it for you.
 24 Q I have it upstairs. We'll figure it

1 out.
2 A It would have been submitted in this
3 general time frame. I don't remember
4 the exact date.
5 Q Now, did you -- did you actually
6 attend -- When did the advisory
7 committee meeting actually take place?
8 A The advisory committee meeting for
9 which this briefing document was
0 prepared was ultimately canceled, and
1 it was rescheduled for January of 2003.
2 Q Did you attend?
3 A Yes.
4 Q Did you make a presentation?
5 A Yes.
6 Q Did your presentation include any
7 reference to the pain data --
8 A No.
9 Q -- that TKT had assembled?
0 A No.
1 Q Had there been a discussion beforehand
2 about whether or not to include pain
3 data at that presentation?
4 A Yes.

1 Q Who did you have that discussion with?
2 A There were many, many, many
3 discussions. I have no idea how many.
4 Q Okay.
5 A People involved in those discussions
6 were Nancy Buc, myself, Neil Kirby, and
7 Dr. Selden at minimum.
8 Q Okay. What view did you express on the
9 subject of whether or not to include
0 references to pain during the
1 presentation?
2 A I felt quite strongly that we needed to
3 present our pain data.
4 Q And why was that?
5 A Because the pain data was the primary
6 endpoint in one of the main controlled
7 studies that we did, and I thought that
8 it was really important to present the
9 results of the study as conducted. I
0 felt very strongly about that for two
1 reasons. The first is I knew FDA was
2 going to present it, and the second
3 was, if we simply ignore our primary
4 endpoint data, I felt and I argued that

1 the advisory committee would
2 potentially question our credibility
3 as, you know, clinician scientists. It
4 would bear on our credibility.
5 Q Do you recall whether Nancy Buc
6 expressed an opinion on whether or not
7 pain data should be included?
8 MR. MARDER: I'm going to
9 object to any conversations with Nancy
10 Buc on the grounds of attorney-client.
11 I instruct you not to
12 answer.
13 MR. HUNTINGTON: Okay. I
14 think they waived, the company's waived
15 that, but we can leave it at that.
16 That's all right.
17 MR. DOUGHERTY: Well, no.
18 We affirmatively sought and that was
19 waived at our request, and we are
20 relying on testimony in this case from
21 Nancy Buc.
22 MR. MARDER: Okay. Well,
23 the company may have waived a privilege
24 that it has with its counsel, but if

1 he -- if she was acting -- well, --
2 MR. HUNTINGTON: Tom's
3 right. There was a supplemental
4 production from the company with
5 documents that related to her files
6 that had been withheld before the
7 waiver.
8 MR. DOUGHERTY: Relatedly,
9 Michael Astrue has given testimony in
10 this matter a couple weeks ago
11 inclusive of his, --
12 MR. HUNTINGTON: Yeah.
13 MR. DOUGHERTY: -- and I
14 will be asking questions, for example,
15 about each of those, with respect to
16 conversations with each of those.
17 MR. MARDER: All right.
18 Well, to the extent -- if the
19 corporation has waived any privilege
20 relating to communications with Nancy
21 Buc, is that what you guys are
22 representing?
23 MR. HUNTINGTON: Yes.
24 MR. MARDER: And if that's

1 the case and he was talking to Mrs. Buc
 2 in his capacity as an employee of TKT,
 3 then on that basis then he can testify.
 4 A I'm sorry, I forgot the question.
 5 Q The question was just, on the subject
 6 of whether or not to include pain as
 7 part of the company's presentation at
 8 the advisory committee meeting do you
 9 recall whether Nancy Buc expressed a
 10 view one way or the other?
 11 A It is my recollection that she
 12 generally agreed with the point I was
 13 making about our credibility as
 14 clinician scientists.
 15 Q Do you recall whether Dr. Kirby
 16 expressed an opinion one way or the
 17 other?
 18 A I don't recall.
 19 Q And Dr. Selden, what opinion did he
 20 express?
 21 A Dr. Selden felt very strongly that we
 22 should not present the data for pain.
 23 Q He did.
 24 Did he say why he felt that

1 should be the case?
 2 A Yes. He said that it would precipitate
 3 a shareholder lawsuit if we were to
 4 present the pain data because we had
 5 not ever disclosed the analysis of the
 6 AUC result analysis.
 7 Q And that's the AUC standing for area
 8 under the --
 9 A Area under the curve. Yes. I'm sorry.
 10 Q Okay. And who had the final vote on
 11 whether or not pain would be included
 12 as part of the presentation?
 13 A Oh, Dr. Selden did.
 14 Q Did you ever -- in that time frame did
 15 you have any discussions with
 16 Dr. Selden about the slide presentation
 17 you had given at the ASHG conference?
 18 A Yes.
 19 Q Can you tell us what happened in that
 20 conversation?
 21 A I reminded Dr. Selden that we had
 22 presented the statistical analysis of
 23 the primary endpoint data with the
 24 repeated measures P value of .021 on

1 the slide that I had presented.
 2 Q Okay. And how did it come to be that
 3 you were reminding him about that
 4 during this conversation?
 5 A We -- one of the discussions in the
 6 week before the advisory committee
 7 unfortunately -- the discussion of
 8 whether or not we should include pain
 9 in the advisory committee unfortunately
 10 was a little heated, and Dr. Selden
 11 asked me to come to his office where
 12 the two of us had a meeting just the
 13 two of us where he -- I told him that
 14 in terms of a shareholder lawsuit,
 15 having the advisory committee go poorly
 16 would be a much worse thing than that
 17 because, if the advisory committee went
 18 poorly, Replagal was not going to be
 19 approved in all likelihood.

20 And Dr. Selden indicated to
 21 me that he was unaware that we had
 22 ever -- he first said to me that he was
 23 unaware that the area under the curve
 24 analysis was not positive, and he

1 suggested to me that I had told him
 2 that. He also suggested to me that he
 3 was unaware that we had presented the P
 4 value on the slide at the ASHG meeting
 5 and that he was unaware at the time.
 6 He was aware of it in January of 2003
 7 when we were talking, and I reminded
 8 him that that was a preposterous
 9 assertion.
 10 Q Okay. Did he respond after you
 11 reminded him?
 12 A Not really.
 13 Q Was that the end of your discussion on
 14 this particular topic?
 15 A Pretty much.
 16 MR. HUNTINGTON: I don't
 17 have any other questions.
 18
 19 EXAMINATION
 20 BY MR. DOUGHERTY:
 21 Q Just picking up on that,
 22 Dr. Schuetz, --
 23 A This?
 24 Q No, just picking up on the last

1 questions there. Just leave that
2 there.

3 Picking up on the last
4 questions from Mr. Huntington, do you
5 recall with respect to a question of
6 TKT pursuing pain at the advisory
7 committee as a basis for the approval
8 of Replagal that in October 2002, so
9 two months before, two or three months
0 before the January conversation that
1 you just eluded to, in October 2002 TKT
2 had publicly announced by press release
3 that it would not be pursuing pain as a
4 basis before the advisory committee for
5 the approval of Replagal?

6 A Yes.

7 Q And TKT had told shareholders and the
8 public that it would not be doing so in
9 that press release; correct?

10 A Yes.

11 Q And, in addition, you'd agree that the
12 briefing book materials, both TKT's and
13 the one you have in front of you, the
14 FDA briefing book, as revised obviously

1 Q -- would become public at the point of
2 the advisory committee meeting? Do you
3 recall knowing that?

4 A Yes.

5 Q And so whatever the various measures
6 were that were referred to in the
7 briefing book, including area under the
8 curve, would become public as part of
9 the advisory committee?

10 A Yes.

11 Q And you knew that to be the case, for
12 example, even at the time that the
13 advisory committee was scheduled for a
14 September advisory committee, that in
15 connection with the advisory committee
16 meeting, whenever it happened, the data
17 would become public that is in the
18 FDA's briefing book?

19 A Yes. That was not the question he
20 asked though.

21 Q I understand.

22 A Okay.

23 Q So at the point that Dr. Selden had a
24 reference to a possibility of a

1 because, as you recall, it got revised
2 over the fall before the January
3 meeting -- Correct?

4 A Did I -- I'm sorry, I didn't understand
5 what it was --

6 MR. MARDER: Object to
7 form.

8 Q We'll go back.

9 A -- in your sentence. I'm sorry.

10 Q We'll go back.

11 Do you recall that in
12 connection with the -- I'll simplify.

13 Do you recall in connection
14 with the advisory committee in January
15 that the FDA's briefing book on the
16 Replagal product itself would become
17 public?

18 A I'm really sorry, I didn't understand
19 the question. Do I --

20 Q Yes.

21 Do you recall that the
22 document that the FDA prepared, its
23 briefing book, --

24 A Yes.

1 shareholder lawsuit in a conversation
2 with you in January of 2002, TKT had
3 already publicly -- January 2003,
4 sorry. Strike that again.

5 At the point that

6 Dr. Selden had a conversation with you
7 in January 2003 about the possibility
8 of shareholder lawsuit, TKT had already
9 told the public and shareholders that
10 it was not going to pursue pain in an
11 October press release, correct, as a
12 basis for approval of Replagal?

13 A Yes, that's correct.

14 Q Okay. So let me go back then.

15 Just starting back at the
16 beginning of questions that
17 Mr. Huntington asked you, he asked you
18 about the possibility of a surrogate
19 approval, and I think that what you
20 said was, and correct me if I'm wrong,
21 that it's a -- its surrogate is part of
22 a specific regulatory pathway that
23 potentially provides for approval
24 faster than showing a clinical benefit

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

RICHARD F. SELDEN,

Defendant.

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**Civil Action No.
05 CV 11805 NMG**

**[PROPOSED]
ORDER BARRING DEFENDANT RICHARD F. SELDEN
FROM ACTING AS AN
OFFICER OR DIRECTOR OF A PUBLIC COMPANY**

Plaintiff, the Securities and Exchange Commission (“Commission”), having filed a Complaint in this action on September 1, 2005; defendant Richard F. Selden having consented on April 16, 2008 to entry of a final judgment; a final judgment having been entered on July 8, 2008; and the Court having considered the Commission’s motion for entry of an order barring Selden from acting as an officer or director of a public company:

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that, pursuant to Section 20(e) of the Securities Act of 1933 (“Securities Act”) [15 U.S.C. § 77t(e)] and Section 21(d)(2) of the Securities Exchange Act of 1934 (“Exchange Act”) [15 U.S.C. § 78u(d)(2)], Selden is barred for a period of five years from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the

Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)].

DONE AND ORDERED at Boston, Massachusetts, this ____ day of
_____, 2008.

UNITED STATES DISTRICT JUDGE